REMARKS

In the Office action, the examiner noted that claims 1-68 were pending in the application, claims 14-68 were withdrawn from consideration, and claims 1-8 and 10-12 were rejected. Claims 1, 2, 5, 8 and 12 have been amended, claims 9 and 13 have been withdrawn, and new claims 69-77 have been added.

It appears the Examiner has argued the claim amendments filed on January 16, 2009 in the Applicant's Amendment After Final Office Action. The Examiner in response was unwilling to enter these amendments as set forth in his Advisory Action dated February 6, 2009. The Applicants have entered the same amendments and will address the Examiner's arguments.

Claim Rejections

Rejections under 35 U.S.C. § 102

Claims 1-3, 6-8 and 10 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 6,041,777 to Faithfull et al. The Applicant submits the claims are not prima facie anticipated by Faithfull et al.

The Examiner alleges that Faithfull teaches an apparatus that comprises a PAP device for sleep therapy and directs the Applicant to col. 21, lines 60-65. In col. 21, lines 60-67 Faithfull states:

> Whatever form is selected, it is clearly within the scope of the present invention to manually or mechanically manipulate the variable volume reservoir so as to effect positive pressure ventilation. This technique is analogous to "bagging the patient" with conventional open-circuit ventilation devices and may be especially useful in emergency procedures.

Faithfull does not teach of a positive airway pressure device for sleep therapy, but rather discloses a closed circuit ventilation device for use with surgery or traumatic disorders such as

> ...lung contusion, diver's lung, post-traumatic respiratory distress, post surgical atelectasis, irritant injuries, septic shock, multiple organ failure, Mendelssohn's disease,

> obstructive lung disease, pneumonia, pulmonary edema...., See col. 1, lines 25-29.

The device in Faithfull is a closed circuit ventilator, col. 6, line 21. The device disclosed is preferably used with liquid ventilation, i.e., the use of fluorochemicals to deliver oxygenation to the subject's lungs. The system in Faithfull is closed circuit to prevent the unintentional loss of valuable materials, such as fluorochemicals, into the environment, col. 6, lines 24-26.

With respect to claims 1-7, Faithfull does not disclose a PAP device for sleep therapy, comprising a source of medical grade carbon dioxide; and an assembly for combining pressurized air from the PAP device with substantially low concentrations of the carbon dioxide resulting in a gas mix as claimed.

Faithfull does not teach or disclose a PAP device for sleep therapy as outlined above. Rather, the embodiment in FIG. 3 of Faithfull in which the Examiner is relying is a passive device which "does not require positive pressure ventilation", col. 20, lines 53-54.

Faithfull does not teach the use of carbon dioxide as a treatment, but rather as an expiratory gas (or by product) that needs to be removed from the closed circuit ventilator. Faithfull uses a unidirectional inspiratory check valve to prevent substantial entry of the expiratory gas to the target or patient, col. 20, lines 64-65. Faithfull also uses a carbon dioxide separator to remove some or all of the carbon dioxide from the expiratory gas. The carbon dioxide in the expiratory gas is respiratory waste – and certainly can't be confused with medical grade carbon dioxide as claimed.

Finally, Faithfull is a closed loop system and therefore by the very definition of a closed loop system cannot teach of an assembly for combining pressurized air from the PAP device with substantially low concentrations of the carbon dioxide resulting in a gas mix as claimed.

With respect to claims 6 and 7, Faithfull does not teach or disclose the device in Claim 1 wherein at least one of the source, the assembly and the PCVSM is a computer processor controlled to modulate concentration of carbon dioxide in the gas mix as claimed. Faithfull instead teaches of an inspiratory gas controller to regulate oxygen.

Faithfull does not teach the modulation of the concentration of carbon dioxide in the gas mix with a controller as claimed.

Further with respect to claim 7, Faithfull does not teach or disclose a PAP device for sleep wherein the computer processor modulates concentration of CO_2 in the gas mix as a function of any combination of sensed concentration of carbon dioxide in the PCVSM, sensed target state and detected system changes as claimed. Nowhere does Faithfull teach, disclose or even imply that carbon dioxide concentration is modulated by a computer processor and certainly not as a function of sensed concentration in the PCVSM, sensed target state or as a matter of detected system changes as claimed.

With respect to claims 8 and 10, Faithfull does not teach or disclose a method with the steps of providing substantially low concentration of medical grade carbon dioxide to a PAP device used for sleep therapy; combining pressurized air from the PAP device used for sleep therapy with the medical grade carbon dioxide to form a gas mix having stabilizing effects on breathing, the pressurized air enabling the carbon dioxide at low concentrations in the gas mix to have stabilizing effects on target respiratory systems; and delivering the gas mix to a subject with the PAP device used for sleep therapy as claimed.

The Applicant incorporates the above remarks. Further Faithfull is a closed loop ventilation system where expired or waste carbon dioxide from the patient is removed from the system. Faithfull does not teach or disclose providing carbon dioxide for sleep therapy, nor mixing medical grade carbon dioxide with pressurized air to have stabilizing effects on a target or patient's breathing as claimed.

Given the reasons set forth above, the Applicant respectfully requests withdrawal of these rejections.

Rejections under 35 U.S.C. § 103

Claims 4, 5, 11, and 12 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Faithfull et al. The Applicant submits the claims are not prima facie obvious in light of these rejections.

With regard to claims 4, 5, 11 and 12, which claim specific concentrations of CO_2 in the gas mix supplied to the patient, the examiner admits that Faithfull does not

quantitatively disclose concentrations of carbon dioxide in the gas mix. Furthermore, Faithfull teaches eliminating carbon dioxide as waste – not adding carbon dioxide for therapeutic purposes. The teachings of Faithfull would lead one skilled in the art to believe that it was necessary to eliminate as much carbon dioxide as possible from the closed loop ventilation system of Faithfull.

The examiner, to the contrary, states that "It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Faithfull's invention by providing a concentration of carbon dioxide in the gas mixture that is between 0.5% and 2% to stabilizing effect on respiration during sleep, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art." The Applicant submits that this "official notice" assertion doesn't make sense, is untrue, and the examiner provides no evidence of this.

As averred in the specification of the application, "Prior to Applicant' discovery of such, use of CO_2 was not considered effective in doses below a concentration of 2%." The "official notice" assertion is untrue because, as averred in the specification, "the stabilizing properties [of CO_2] at low doses (less than 2%) when given in conjunction with PAP as discovered by Applicant are heretofore not documented or known. No equipment is currently available to deliver CO_2 and pressurized air in precisely metered combinations, either in a clinical or home setting. Precise metering of these gases is essential for therapeutic use since both gases, and especially CO_2, have the potential for adverse side effects if an overdose is given. Metering must be maintained over a range of demand conditions." Use of this precise metering is not of "routine skill in the art" and the invention claimed was not a discovery of "optimum or workable ranges".

The examiner has also failed to introduce factual evidence supporting this "official notice" assertion. The MPEP requires the examiner to "provide specific factual findings predicated on sound technical and scientific reasoning to support his or her conclusion of common knowledge [or what is 'routine skill in the art' as alleged by the examiner]." See MPEP § 2144.03 B. The MPEP also requires the examiner to "'point to some concrete evidence in the record in support of these findings' to satisfy the substantial evidence test. If the examiner is relying on personal knowledge to support the

finding of what is known in the art, the examiner must provide an affidavit or declaration setting forth specific factual statements and explanation to support the finding." MPEP § 2144.03 C (emphasis added).

In addition, establishing the level of ordinary skill in the art is critical to a proper obviousness inquiry in that it maintains the objectivity of the obviousness inquiry and serves as a means of preventing fact finders "from using their own insight or, worse yet, hindsight, to gauge obviousness." Okajima v. Bourdeau, 261 F.3d 1350, 1355 (Fed. Cir. 2001). Further, clear and early definition of the level of ordinary skill in the art by the fact finder is all the more critical to an applicant for patent in light of the Supreme Court's recent decision in KSR v. Teleflex, 127 S. Ct. 1727 (2007), wherein the Court reemphasized the prominent and vital role to be played in the obviousness inquiry by the person of ordinary skill in the art.

The Applicant also suggests that based on the record before us in this case what would have been obvious to a person of ordinary skill in the art at the time of the invention must be in the personal knowledge of the examiner, and request that he therefore with his next Office action submit an affidavit detailing as specifically as possible the personal knowledge upon which his rejection is based. See 37 C.F.R. § 1.104(d)(2).

Given the reasons set forth above, the Applicant respectfully requests withdrawal of these rejections.

CONCLUSION:

The Applicant respectfully submit that this application is in condition for allowance and that action is earnestly solicited.

Respectfully submitted,

9/17/2009
Dated

Brian M. Kolkowski
Reg. No.: 36,847
Attorney for the Applicant, and
Cleveland Medical Devices Inc.
4415 Euclid Avenue, Suite 400
Cleveland, Ohio 44103
(216) 649-0376
Fax: (216) 649-0397
E-mail: bkolkowski@clevemed.com

Cc: Dr. Catherine Lenich
Mary Lou Wakimura, Esq.